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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 017227/0159

In re patent application of
Suzanne CORY *et al.*

Serial No. 09/508,832

Group Art Unit: 1642

Filed: July 10, 2000

Examiner: M. Yu

For: **NOVEL THERAPEUTIC MOLECULES**

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REQUEST FOR RECONSIDERATION AND REVIEW TECH CENTER 1600/2900

DECISION ON PETITION TO THE GROUP DIRECTOR

Group Director
Art Unit 1600
Washington, D.C. 20231

Sir:

Applicants hereby request reconsideration of a decision on petition, dated December 12, 2002 (hereafter, "the decision"), in relation to the above-captioned application. This request, which incorporates by reference the action requested, the statements of fact, and the argument from the underlying petition, is timely filed within two months of the mailing date of the decision.

Should additional fees be necessary in connection with the filing of this paper, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees.

Argument

(A) "Examples" proffered in the relevant administrative guidance are not exclusive, as the decision treats them, but rather are illustrative only

In at least two instances, the decision disposes of applicants' arguments by concluding, in effect, that the claims at issue are not "in the form" or "of the type" embodied in an "example" of the relevant administrative guidance. This rationale is advanced in relation to (i) Example 17 of Annex B of the PCT administrative instruction (decision, paragraph bridging pages 1 and 2) and (ii) "examples subject to the partial waiver of 37 CFR 1.141" (*id.*, last full paragraph on page 2).

By definition, an example is “a particular single item...or aspect that is representative of all of a group or type,” or “an instance...serving to illustrate a rule or precept.”

WEBSTER’S NEW COLLEGiate DICTIONARY (1981). The antithesis of this meaning, with its emphasis on “representative” and “illustrate,” is the decision’s erroneous invoking of examples to impose *per se* limits on the guidances in question. Moreover, both the Commissioner’s pronouncement, 1192 O.G. 68 (Nov. 19, 1996), and the PCT administrative instructions are presumed to have the force of law and, hence, cannot be constrained by a preclusive agency interpretation promulgated, for example, under the MANUAL OF PATENT EXAMINING PROCEDURES.

Even from the perspective of the decision regarding Group X claims, therefore, it is wholly improper for the decision to conclude that, because “the [present] fact situation is not analogous to Example 17” of the PCT administrative instructions], “the conclusion drawn in that example does not apply.” The rule or precept *illustrated* by Example 17, that it is improper to restrict between a protein and an encoding polynucleotide, *does* apply to the present fact situation. Similarly applicable is the precept of Commissioner’s 1996 pronouncement, which is the accommodation of “reasonable” number of sequences, thereby “to aid the biotechnology industry...without creating an undue burden on the Office.” Again, this principle should not and cannot be abrogated, as the decision purports to do, on the strength of illustrative examples in the MPEP.

(B) The decision on petition should have addressed the reasonableness of examining closely related sequences

Applicants’ petition requested, *inter alia*, (i) examination together of claims reciting SEQ ID No: 9 or No: 10 and (ii) modification of the restriction between Groups V and Groups I-IV, such that at least two and preferably five polynucleotide sequences would be examined together. For each of requests (i) and (ii), applicants advanced a substantive refutation of the examiner’s stated grounds for restriction, namely, the lack of a technical feature that defines a contribution over the prior art. Thus, applicants presented evidence, in the form of an alignment analysis (petition, page 3), and identified specific structural similarities (*id.*, page 4) to demonstrate, respectively, their compliance with PCT rules and the involvement of only “a reasonable number” of sequences, consistent with the Commissioner’s 1996 pronouncement.

The decision says nothing about the proffered evidence as such, contending only that the claims at issue, for one reason or another, may encompass “many nucleic acid sequences which need not be closely related to SEQ ID NO: 10.” Even if this characterization were accepted, *arguendo*, applicants’ refutation of the cited prior art would stand, leaving no reference or combination of record that effectively undercuts the patentability of the claims, however interpreted. Thus, the decision is without basis in concluding, simply on allegations related to claim breadth, that “the claims as written are not free of the prior art.” What “prior art”?

Conclusion

For the foregoing reasons, applicants request reconsideration or review of the decision, to the extent that applicants’ request was denied for: (A) withdrawal of restriction between SEQ ID No: 9 and No: 10; and (B) examination together of at least the human Bim_{EL} (SEQ ID No: 9) and Bim_L (SEQ ID No: 7) nucleic acid sequences, legitimately with murine Bims (SEQ ID No: 1), Bim_L (SEQ ID No: 3), and Bim_{EL} (SEQ ID No: 5) polynucleotides, too.

Respectfully submitted,



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12 February 2003

Date

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